



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Food and Drug Administration  
New England District

*Putzed - 1/14/99  
M&D*

*HFI-35 m2309n*

Food and Drug Administration  
One Montvale Avenue  
Stoneham, Massachusetts 02180  
(781)279-1675 FAX: (781)279-1742

January 8, 1999

**WARNING LETTER**

**NWE-06-99W**

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

David J. Page, President  
D & C Fish Inc.  
83 State Street  
Narragansett, RI 02882

Dear Mr. Page:

On October 27-28, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 83 State Street, Narragansett, RI 02882. The Investigators documented serious violations of the seafood processing regulations in Title 21, Code of Federal Regulations (21 CFR) Part 123 "Safe and Sanitary Processing and Importing of Fish and Fishery Products" (Seafood HACCP Regulation) causing the seafood products being processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, as follows:

- Failure to monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in Title 21 of the Code of Federal Regulations (CFR) Part 110 that are both appropriate to the plant and the food being processed and related to the safety of the water; the conditions and cleanliness of food contact surfaces; the prevention of cross-contamination from insanitary objects; the maintenance of hand washing, hand sanitizing, and toilet facilities; the protection of food, food packaging material, and food contact surfaces from adulteration; the proper labeling, storage, and use of toxic compounds; the control of employee health conditions; and the exclusion of pests (21 CFR 123.11(b)).

David J. Page, President  
D & C Fish Inc.  
Narragansett, RI 02882  
January 8, 1999  
Page 2

- Failure to maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed in 21 CFR 123.11(b) (21 CFR 123.11(c)).

The above identified violations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with the Act and the requirements of the federal regulations.

FDA will not issue any certificates of export for any of the seafood products processed at your facility until your firm is fully in compliance with the seafood HACCP regulations. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675, Extension 113.

Sincerely,



John R. Marzilli

District Director  
New England District Office